

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-08 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-06

MED-03 EB-07 COME-00 /072 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

AF/S:FBCRUMP(INFO)

NEA/EX:EGABINGTON(INFO)

ARA/EX:GECHAFIN(INFO)

EA/EX:JRCUNNINGHAM(INFO)

EUR/EX:CEREDMAN(INFO)

----- 043522

R 182311Z AUG 76

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

AMEMBASSY VIENNA

AMEMBASSY BOGOTA

AMEMBASSY COPENHAGEN

AMEMBASSY HELSINKI

AMEMBASSY PARIS

AMEMBASSY REYKJAVIK

AMEMBASSY TEHRAN

AMEMBASSY TEL AVIV

AMEMBASSY ROME

AMEMBASSY TOKYO

AMEMBASSY BEIRUT

AMEMBASSY KUALA LUMPUR

AMEMBASSY MEXICO

AMEMBASSY BRASILIA

AMEMBASSY THE HAGUE

AMEMBASSY WELLINGTON

AMEMBASSY OSLO

AMEMBASSY MANILA

AMEMBASSY JIDDA

AMEMBASSY PRETORIA

AMEMBASSY MADRID

AMEMBASSY DAMASCUS

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AMEMBASSY STOCKHOLM

AMEMBASSY BERN
AMEMBASSY TAIPEI
AMEMBASSY BANGKOK
AMEMBASSY ANKARA
AMEMBASSY MOSCOW
AMEMBASSY LONDON
AMCONSUL HONG KONG
AMCONSUL SAO PAULO
AMEMBASSY BRASILIA

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E.O. 11652: N/A

TAGS: OGEN, EIND, ETRD, TBIO, AS, AU, BR, CO, DA, FI
FR, HK, IC, IR, IS, IT, JA, LE, MY, MX, NL,NZ, NO, RP, SA,
SF, ST, SY, SW, SZ, CH, TH, TU, UR, UK
CSJ: FDA ADVISORY - DEFECTIVE CUFF ON TRACHEOSTOMY
TUBES ENDOTRACHEL TUBES - RECALL NOS. T-113/4-6

1. FDA ADVISES OF THE FOLLOWING RECALLS:

PRODUCTS INVOLVED: A-T-113-6 - LANZ CONTROLLED PRESSURE
CUFF TRACHEOSTOMY TUBE WITH OBTURATOR. ALL SIZES. PACKED
IN STERILE ENVELOPE WITH ONE TRANSPARENT SIDE. SHIPPED IN
MULTIPLE UNIT CARDBOARD BOX.

-- B. T-114-6 - LANZ CONTROLLED PRESSURE
CUFF ENDOTRACHEAL TUBE. ALL SIZES. PACKED IN STERILE EN-
VELOPE WITH ONE TRANSPARENT SIDE. SHIPPED IN MULTIPLE UNIT
CARDBOARD BOX.

PRODUCT IDENTIFICATION: ALL PRODUCTS LABELED AS MANUFAC-
TURED BY LANZ MEDICAL PRODUCTS CORPORATION; MARKETING BY -
EXTRA CORPoreal INC., ROYAL AND ROSS ROADS, KING OF PRUSSIA,
PA 19406. NO PRIVATE LABELS ARE INVOLVED. ALL LOT NO. AND
ALL SIZES ARE BEING RECALLED.

RECALLING AND RESPONSIBLE FIRM: EXTRA CORPoreal MEDICAL
SPECIALITIES INC., ROYAL AND ROSS ROADS, KING OF PRUSSIA,
PA 19406, TEL. NO. 215-337-2400. THIS FIRM STERILIZES AND
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MARKETS PRODUCTS. THEY ARE RESPONSIBLE FOR FINAL QUALITY
ASSURANCE OF PRODUCTS.

MANUFACTURING FIRM: LANZ MEDICAL PRODUCTS CORPORATION,
WILMERDING, PA. THIS FIRM ASSEMBLES PRODUCTS FROM COM-
PONENTS AND PACKAGES PRODUCTS.

COMPONENT MANUFACTURER: NATIONAL CATHETER CORPORATION,
ARGYLE, N.Y. THIS FIRM MANUFACTURES TUBING USED IN ENDO-
TRACHEAL TUBE.

2. REASON FOR RECALL: ONE COMPONENT USED IN THE MANU-
FACTURER OF BOTH PRODUCTS HAS BEEN DEVELOPING DEFECTS IN
THE FORM OF CRACKS IN THE MATERIAL. THE FIRM BECAME AWARE
OF THE PROBLEM THROUGH CUSTOMER COMPLAINTS. THE DEFECTIVE
PART IS THE HOUSING FOR THE PRESSURE REGULATING VALVE.
THIS PART IS MADE OF POLYSTYRENE. CRACKS IN THIS HOUSING
MAY PERMIT AIR LEAKAGE AND COLLAPSE OF THE INFLATED CUFF
WHICH IS DESIGNED TO REMAIN INFLATED INSIDE THE TRACHEA TO
PROVIDE AN AIRTIGHT SEAL AND TO PREVENT THE DEVICE FROM
MOVING ONCE IT HAS BEEN CORRECTLY PLACED. ON MAY 24, 1976
THE FIRM ISSUED AN URGENT MEDICAL DEVICE RECALL CONCERNING
THE DEFECTIVE DEVICES. THE LETTER REQUESTS DISCONTINUANCE
OF USE AND IMMEDIATE RETURN BY SUITABLE TRANSPORTATION OF
THE DEFECTIVE DEVICES. INSTRUCTIONS ARE INCLUDED FOR SAFE
USE OF THE DEFECTIVE UNITS AT THE OPTION OF A PHYSICIAN.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED RECALL LETTER DATED MAY
24, 1976. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING
RECALLS SHOULD BE DIRECTED TO THE FIRMS.

4. FOREIGN CONSIGNEES AS FOLLOWS:

OY CHRISTIAN NISSEN AB
LAIPPATIE 9
P O BOX 21
00811 HELSINKI 81 FINLAND

AMERICAN EMBASSY DAMASCUS
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SYRIAN ARAB REPUBLIC
FOR USA PAVILLION
DAMASCUS INT'L AIRPORT SYRIA
FOR DAMASCUS INT'L FAIR

AUSTURBAKKI
BOX 1282
REYKJAVIK, ICELAND

C. BRADY
HORLGASSE 5
A-1092 VIENNA, AUSTRIA

CIENTEC IMPORTACAO E.
COMMERCCIO LTDA

RUA GABRIEL DOS SANTOS 125
SAO PAULO SP BRAZIL

CLIMO SA
39 BOULEVARD AMBROISE PARE
69008 LYON FRANCE

RICHARD DUMBAKLY
MAR MANSOUR
BECHARA EL KHOURY ST
BEIRUT, LEBANNON

EUROSPITAL S.P.A.
VIA FLAVIA 122/124
34147 TRIESTE, ITALY

EMSCO CO., LTD.
6TH FLOOR, MORIFUJI BUILDING
2-29 BENTEN-DORI NAKA-KU
YOKOHAMA-SHI
JAPAN 231

N. V. FRANITAL
C/O FRANKEN AND ITALLIE
P O BOX 869
AMSTERDAM, HOLLAND
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DR. E. FRESENIUS KG
GLUCKENSTEINWEG 5
638 BAD HOM BURG VDH
GERMANY

FVA EX-IM TRADING INC.
P O BOX 1851
MAKATI COMMERCIAL CTR.
MAKATI RIZAL
PHILIPPINES

HAUSMANN HOSP. SUPPLY LTD.
MARKTGASSE 11
CH9001 ST. GALL
SWITZERLAND

HOSPITAL UNIVERSITARIO DEL VALLE
CALLE 5 NO. 36-80
CALI, COLOMBIA

INN KAUPASTOFNUN

REYKJAVI KUR BORGAR
REYKJAVIK PURCHASING CTR
FRIKIRKJUVEGI 3 REYKJAVIK
SIMI 25800 ICELAND

ISRAMED COM
P O BOX 4942
TEL-AVIV, ISRAEL

KUPAT HOLIM HEALTH SVC
KOVELMAN HOUSE
146 PETAH TIQVA RD
TEL-AVIV, ISRAEL

CHI LEE COMPANY LTD
RMS 60116 JARDINE BLDG
6TH FLLOR
NOS 14-16 REDDER ST
HONG KONG
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MDE LTD PARTNERSHIP
85 SUKUMVIT 68
BANGKOK, THAILAND

MEDICO A/S
BYGDOY ALLE 33
OSLO 2 NORWAY

MOVI SPA
VIA CASSIO DIONE, 15
20138 MILAON
ITALY

MUTUAL TRADING CO LTD
P O BOX 22148
TAIPEI, TAIWAN
REPUBLIC OF CHINA

NIKKISO CO LTD
NO 43 2 EBISU 3 CHOME
SHIBUYA KU
TOKYO, JAPAN

EBOS DENTAL AND SURG.
SUPPLIES LTD
324 CASHEL ST
CHRIST CHURCH, NEW ZEALAND

ATTN. CHIEF OF ANESTHESIOLOGY

E I PARRISH SDN HERHAD
P O BOX 2063
KUALA LUMPUR
MALAYSIA

PULLMAN INC
COMMERCIAL OFFICE
AMERICAN EMBASSY
HELSINKI, FINLAND

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ATTN. CHIEF OF ANESTHESIOLOGY

REPRESENTACIONES MEDICOTECNICAS
S A
MAZATLAN NO 83
MEXICO 11 D.F.

ATTN. CHIEF OF ANESTHESIOLOGY

DR. JORGE REYNOLDS P
INDUSTRIA COLOMBIANA DE
PRODUCTOS ELECTROFISIOLOGICOS
APARTADO AEREO 8036
BOGOTA, COLOMBIA

ATTN. CHIEF OF ANESTHESIOLOGY

SALEHIYA EST
RIYADH
SAUDI ARABIA

ATTN. CHIEF OF ANESTHESIOLOGY

SIMONSEN AND WEELS EFIF A S
ROSKILDEVEJ 14 DK 2620
ALBERISLUND, DENMARK

ATTN. CHIEF OF ANESTHESIOLOGY

A E STANSEN AND CO PTY LTD.
P O BOX 118 MOUNTY WAVERLEY
VICTORIA 3149 AUSTRALIA

ATTN. CHIEF OF ANESTHESIOLOGY

A B STILLE WERNER

BONDEGATAN 21
S-102 61 STOCKHOLM, SWEDEN

ATTN. CHIEF OF ANESTHESIOLOGY

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SYRMED
P O BOX 2692
DAMASCUS SYRIAN ARAB REPUBLIC

ATTN. CHIEF OF ANESTHESIOLOGY

TEHERAN SUTURES LTD
357 SOUTH FAHLAVI AVE
P O BOX 8-6274
TEHERAN, IRAN

ATTN, CHIEF OF ANESTHESIOLOGY

PULLMAN INC
NO 7
LAUNACHARSKOTO U 1
NOSCOW G-2 USSR

ATTN. CHIEF OF ANESTHESIOLOGY

CHARLES F. THACKRAY LIMITED
P O BOX 171
10 PARK STREET
LEEDS 1 ENGLAND

ATTN. CHIEF OF ANESTHESIOLOGY

CAVIT TULCA
AY HAN 506 ISIIKAL C 354
P O BOX 525
BEYOGLU, ISTANBUL
TURKEY

ATTN. CHIEF OF ANESTHESIOLOGY

M J WINKLER ELECTRONICS PTY
12 IVANSETH RD
REVVEN JOHANNESBURG
SOUTH AFRICA

EXTRACORPOREAL SA
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253 AVENUE WINSTON CHURCHILL
BOX 10
B-1180 BRUSSELS, BELGIUM

ATTN. CHIEF OF ANESTHESIOLOGY

N V FRANTAL
C/O FRANKEN AND ITALLIE
P O BOX 869
AMSTERDAM, HOLLAND

PRIM S A
JORGE JUAN 141
MADRID 28
SPAIN

ATTN. CHIEF OF ANESTHESIOLOGY

AB STILLE WERNER
BONDEGATAN 21
S-102 61 STOCKHOLM
SWEDEN

AKADEMISCH ZIEKENNIS
SINT RAFAEL
KAPUCIJNENVOER 35
3000 LEUVEN BELGIQUE

ATTN. CHIEF OF ANESTHESIOLOGY

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IVERSITE CATHOLIQUE DF LOUVAIN
CLINIQUES UNIVERSITAIRES
ST-PIERRE SERVICI DUACHAT
BRUSSELLESTRAAT 69
3000 LEUVEN, BELGIUM

HOPITAL UNIVERSITAIRE
SAINT PIERRE
320 RUE HAUTE
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1000 BRUXELLES, BELGIUM

ATTN. CHIEF OF ANESTHESIOLOGY

HOPITAL UNIVERSITAIRE BRUGMANN
PLACE A VAN CEHUCHTEN 4
1020 BRUXELLES, BELGIUM

ATTN. CHIEF OF ANESTHESIOLOGY

ST ELIZABETH ZIEKENHUIS
COMMISSIE VAN OPENBARE
ONDERSTAND
RUBENSSTRAAT 166
2300 TURNHOUT BELGIQUE

ATTN. CHIEF OF ANESTHESIOLOGY KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 18 AUG 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE205730
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760317-1178
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19760841/aaaabjhd.tel
Line Count: 453
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 9
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: CunninFX
Review Comment: n/a
Review Content Flags:
Review Date: 22 MAR 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <22 MAR 2004 by ReddocGW>; APPROVED <24 JAN 2005 by CunninFX>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
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Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: n/a
TAGS: OGEN, EIND, ETRD, TBIO, AS, AU, BR, CO, DA, FI, FDA
To: CANBERRA
VIENNA
MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006